

7(Amended). A method for expressing a transgene in a skeletal muscle cell, comprising the step of introducing into the cell a recombinant adeno-associated virus (rAAV) comprising a transgene operably linked to sequences which control its expression, wherein the rAAV is at least as free of contamination with a helper virus as is obtained by subjecting the rAAV to four rounds of cesium chloride gradient centrifugation and wherein the transgene is expressed in the cell.

D2

8(Amended). The method according to claim 7, wherein the transgene encodes a secretable protein.

9(Amended). The method according to claim 8, wherein the protein is selected from the group consisting of Factor IX,  $\beta$ -interferon, insulin, erythropoietin, growth hormone, and parathyroid hormone.

10(Amended). The method according to claim 7, wherein the rAAV consists essentially of, from 5' to 3', 5' AAV inverted terminal repeats (ITRs), a heterologous promoter, the transgene, a polyadenylation sequence, and 3' AAV ITRs.

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D3

~~12(Amended). A recombinant adeno-associated virus (AAV) comprising sequences encoding factor IX and regulatory control sequences which permit expression of factor IX in a cell, wherein the rAAV is at least as free of adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.~~

13(Amended). A composition comprising a physiologically compatible carrier and a recombinant adeno-associated virus (AAV) comprising sequences encoding factor IX and regulatory control sequences which permit expression of factor IX in a cell, wherein the rAAV is at least as free of adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.

Kindly add new claims 18 - 24 as follows.

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E2  
of: 18. A method of delivering a transgene to a mammal comprising the step  
of:  
administering intramuscularly to a mammal a composition comprising  
a biologically compatible carrier and a recombinant adeno-associated virus (rAAV)  
comprising a transgene encoding a secretable protein operably linked to sequences  
which control expression thereof, wherein said rAAV is substantially free of  
contamination with an adenovirus, wherein said rAAV is at least as free of adenoviral  
helper virus as is obtained by subjecting said recombinant AAV to four rounds of  
cesium chloride gradient centrifugation, whereby the protein is secreted from rAAV-  
transduced muscle cells.

19. The method according to claim 18, wherein the composition comprises  
about  $1 \times 10^8$  to about  $5 \times 10^{11}$  particles of the rAAV.

20. The method according to claim 18, wherein the composition comprises  
at least  $10^9$  particles of the rAAV.

21. The method according to claim 18, wherein the composition comprises  
 $10^{12}$  to  $10^{13}$  genomes of the rAAV per milliliter carrier.

22. The method according to claim 18, further comprising the step of  
monitoring expression of the transgene in the mammal.

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23. The method according to claim 18, wherein the level of contaminating  
adenoviral helper virus is the same as that obtained by subjecting said recombinant  
AAV to four rounds of cesium chloride centrifugation.

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24. ~~The composition according to claim 13, wherein the level of contaminating adenoviral helper virus is the same as that obtained by subjecting said recombinant AAV to four rounds of cesium chloride centrifugation.~~

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